Substitute fo	or form 1449A&B/PTO			Complete if Known		
				Application Number	10/731,299	
INFO	RMATION DIS	CLOS	URE	Filing Date	December 8, 2003	
STAT	STATEMENT BY APPLICANT			First Named Inventor	Karimisetty, Srikanth	
				Art Unit	2135	
(Use as many sheets as necessary)				Examiner Name	Nirav B. Patel	
Sheet	1	of	1	Attorney Docket Number	021756-005200US	

Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant
		Number Kind Code ^{2 (Finour)}			Figures Appear
/NP/	1	US-5,560,005	09-24-1996	Hoover et al.	
/NP/	2	US-5,724,575	03-03-1998	Hoover et al.	
/NP/	3	US-5,884,321	03-16-1999	Meffert	
/NP/	4	US-7,093,207	08-15-2006	Liao et al.	
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				FOREIGN	PATENT DOCUM	MENTS		
Examiner Initials*					Name of Patentee or Applicant of Cited Document		T-6	
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			U.S. PATENT DO	CUMENTS	
Examiner Initials*	Cite No.1	Document Number Number Kind Code ^{2 (LAXXWR)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/NP/	1	5,434,917	07-18-1995	Naccache et al.	
	2	5,504,818	04-02-1996	Okano	
	3	5,978,475	11-02-1999	Schneier et al.	
	4	6,240,407	05-29-2001	Chang et al.	·
	5	6,295,513	09-25-2001	Thackston	
	6	6,366,934	04-02-2002	Cheng et al.	
	7	6,796,489	09-28-2004	Slater et al.	
	8	6,807,633	10-19-2004	Pavlik	
	9	6,820,082	11-16-2004	Cook et al.	
	10	6,928,396	08-09-2005	Thackston	
	11	6,959,281	10-25-2005	Freeling et al.	
	12	6,983,423	01-03-2006	Dvorak et al.	
	13	7,039,805	05-02-2006	Messing	
	14	7,089,235	08-08-2006	Dettinger et al.	
	15	7,136,873	11-14-2006	Smith et al.	
	16	7,174,328	02-06-2007	Stanoi et al.	
	17	7,185,192	02-27-2007	Kahn	
	18	7,228,300	06-05-2007	Lei et al.	
	19	2001/0002485	05-31-2001	Bisbee et al.	
	20	2002/0010764	01-24-2002	Spicer .	
	21	2002/0049670	04-25-2002	Moritsu et al.	
	22	2002/0156756	10-24-2002	Stanley et al.	
	23	2002/0157006	10-24-2002	Narishima et al.	
	24	2003/0009295	01-09-2003	Markowitz et al.	
	25	2003/0065936	04-03-2003	Wray	
	26	2003/0131241	07-10-2003	Gladney	
	27	2003/0149608	08-07-2003	Kall etal.	
	28	2003/0150908	08-14-2003	Pokorný et al.	
	29	2003/0177041	09-18-2003	Millican et al.	
	30	2003/0196108	10-16-2003	Kung	<u> </u>
	31	2003/0200130	10-23-2003	Kall etal.	
	32	2004/0039706	02-26-2004	Skowron et al.	
1/	33	2004/0068757	04-08-2004	Heredia	
V	34	2004/0236660	11-25-2004	Thomas et al.	
/NP/	35	2005/0102158	05-12-2005	Maeda, Chris	

Examiner		Date	444000007
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Subs	stitute for form 1449A/PTQ			Complete if Known		
				Application Number	10/731,299	
	FORMATION DIO		OUDE	Filing Date	December 8, 2003	
	INFORMATION DISCLOSURE			First Named Inventor	Karimisetty, Srikanth	
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	(Use as many sheets as necessary)			Examiner Name	Nirav B. Patel	
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	U.S. PATENT DOCUMENTS								
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/NP/	36	2005/0108153	05-19-2005	Thomas et al.					
/NP/	37	2005/0132201	06-16-2005	Pitman et al.					
/NP/	38	2005/0240770	10-27-2005	Lane et al.	·				

			FOREIGN	PATENT DOCU	MENTS		
Examiner Cite Initials* No.	Foreign Patent	Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
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INFO	RMATION DIS	CLOS	URE	Filing Date	December 8, 2003	
STAT	STATEMENT BY APPLICANT			First Named Inventor	Karimisetty, Srikanth	
				Art Unit	2135	
((Use as many sheets as necessary)			Examiner Name	Nirav B. Patel	
Sheet	3	of	4	Attorney Docket Number	021756-005200US	

		NON PATENT LITERATURE DOCUME	NTS					
Examiner Initials *	CILE I							
/NP/ 39		BERTINO et al. "Integrating XML and Databases" IEEE Internet Computing July-Aug 2001						
	40	CHUEH et al., "An XML Portable Chart Format," 1998, F	Proc AMIA S	ymp., pp. 730-734.				
	41	FDA, Guidance for Industry Part 11, Electronic Records, Application, Aug. 2003.	; Electronic S	Signatures - Scope and				
	42	MATHIESON, "Implementing Oracle Workflow," European Oracle User Group 1999 Presentation pages 1-11						
	MEEHAN, "Deploying Hummingbird Document and Records Management Products to Corwith 21 CFR Part 11:Electronic Records; Electronic Signatures," April 2003, Hummingbird.							
- 0000	44	MUIRHEAD, "Impact of 21 CFR Part 11 on clinical labor American Clinical Laboratory, pp. 33-34.	atories: An o	overview," Aug. 2001,				
	45	NOFERI et at. "Information Age Audits" BioPharm Jan 2	2002 pgs 35-	39 and 50				
	46	ORACLE, "Oracle Workflow Release 2.6.2 Business Ev Guidelines October 2001 26 pages	ent System a	and PL/SQL Development				
	47	ORACLE, "Question & Answer Document for Oracle Ap	psworld" Jan	nuary 19-22, 2003 pg 1-81				
	48	ORACLE, Oracle Life Sciences Platform Feature Summ	ary, Feb. 20	03, Oracle Corp.				
/NP/	49	PAPAZOGLOU, "The World of e-Business: Web-Service Transactions" WES 2002, LNCS 2512, pp 153-173,2002		s, and Business				
Examiner Signature		/Nirav Patel/	Date Considered	11/16/2007	1			

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				Art Unit	2135	
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. /NP/	50	SmarTeam, SMARTEAM - FDA Compliance Configuration (SFA), IBM/SmarTeam, Sep. 2003.					
. /NP/	51	SmarTeam, SMARTeam [™] FDA Compliance Technical Paper Functional Compliance With FDA Rule 21 CFR Part 11, July 2002, SMARTEAM Corp.					
/NP/	52	STEMBER, LABTrack: Introducing a legal electronic lab notebook, 221st National Meeting, American Chemical Society, Division of Chemical Information.					

Examiner Signature	/Nirav Patel/	Date Considered	11/16/2007

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